

DEVICE FOR PERFORMING A DIAGNOSTIC TEST AND METHODS FOR USE THEREOF**RELATED APPLICATIONS**

[0001] This application claims the benefit of and priority to U.S. Prov. Pat. App. Ser. No. 61/625,368 filed 17 Apr. 2012 and U.S. Prov. Pat. App. Ser. No. 61/740,975 filed 21 Dec. 2012, the entireties of which are incorporated herein by reference.

BACKGROUND

[0002] Sampling and testing of biological samples and body fluids (e.g., saliva, blood, urine, fecal matter, foods, plants, fish, minerals, animals, etc.) is common for both testing and monitoring humans, fish, animals, and plants for any number of biochemical or physiological conditions and, of course, for determining the general state of health of an organism. For example, sampling and testing of human body fluids is often performed for point-of-care testing ("POCT"). POCT is defined as medical testing at or near the site of patient care. The driving notion behind POCT is to perform and provide the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results more quickly and allows for immediate clinical management decisions to be made. POCT examples include, but are not limited to, blood glucose testing, metabolic testing (e.g., thyroid stimulating hormone), blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine testing, pregnancy testing, fecal occult blood analysis, food pathogen screening, hemoglobin diagnostics, infectious disease testing, cholesterol screening, cancer testing (e.g., PSA), hormone testing (hCG, LH, FSH), cardiac (troponin), pulmonary, gastroenterology (e.g., *H. pylori* antibodies), urology, dermatology, neurology, pediatrics, surgical, and public health (Ebola, cholera, HIV), testing and combinations thereof.

[0003] One testing method that is often employed for POCT and more conventional testing involves the use of lateral-flow chromatographic immunoassay cassettes. Lateral-flow chromatographic immunoassay cassettes can be used to easily and quickly obtain a variety of qualitative results relating to a number of biochemical and physiological conditions and disease states of an individual. These kinds of tests require the end user to simply add a sample to the cassette and then observe the result a few minutes later. Since such rapid and easy-to-use tests are user friendly, they are very popular in both the professional and consumer markets nowadays. Such tests are also widely used in areas where access to trained health care professionals is limited or where access to proper medical facilities is limited (e.g., poor areas, developing countries, war zones, etc.).

[0004] Lateral flow chromatographic immunoassay methods and devices have been described extensively. See, e.g., Gordon and Pugh, U.S. Pat. No. 4,956,302; H. Buck, et al., WO 90/06511; T. Wang, U.S. Pat. No. 6,764,825; W. Brown, et al., U.S. Pat. No. 5,008,080; Kuo and Meritt, U.S. Pat. No. 6,183,972, EP 00987551A3. Such assays involve the detection and determination of an analyte substance that is a member of a specific binding pair consisting of a ligand and a receptor. The ligand and the receptor are related in that the receptor specifically binds to the ligand, being capable of distinguishing a specific ligand or ligands from other sample

constituents having similar characteristics. Immunological assays involving reactions between antibodies and antigens are one such example of a specific binding assay. Other examples include DNA and RNA hybridization reactions and binding reactions involving hormones and other biological receptors. One well-known commercial embodiment of this technique is the Clearblue One-Step Pregnancy Test.

[0005] Lateral flow chromatographic immunoassay test cassettes have a number of desirable characteristics including their ease of use and broad applicability to a variety of analytes. Likewise, immunoassay procedures capable of being carried out on a test strip and which can be administered in the field or other locations where medical testing laboratories are not readily available have provided a great benefit to the diagnosis and control of disease. Currently, however, such lateral flow chromatographic immunoassay tests are generally only capable of providing qualitative results. That is, while currently available lateral flow chromatographic immunoassay test cassettes and cassette reader apparatuses are particularly well-suited for telling a practitioner whether or not one or more test substances are present in a sample above a given detection limit, they are poorly suited for providing quantitative results. There is an ongoing need in the art for devices and methods that combine the ease of use characteristics of lateral flow chromatographic immunoassay tests with systems that are designed to provide quantitative results. Such devices and methods may, for example, allow medical practitioners to diagnose, monitor, and manage a variety of conditions at the point of care (e.g., chair-side or essentially anywhere in the world) without being tied to a medical facility or a testing laboratory.

BRIEF SUMMARY

[0006] Devices and methods for performing point of care diagnostic tests for detecting and quantifying at least one analyte in a biological sample (e.g., a body fluid). Disclosed herein are assay cassettes and testing devices that can be used to provide rapid, accurate, affordable laboratory-quality testing at the point of care. Such assay cassettes and testing devices are designed to provide rapid, quantitative test results in a point-of-care setting or the like where, in the past, only qualitative or semi-quantitative results have typically been available. Likewise, such assay cassettes and testing devices may eliminate or replace expensive, centralized clinical testing equipment and technical personnel. Such testing devices may include automated data reporting and decision support.

[0007] In one embodiment, a diagnostic test system is disclosed. The system includes a lateral-flow chromatographic assay cassette and a compact, portable testing device that includes data collection and data analysis capabilities. The testing device is configured to interface with and analyze output of the lateral-flow chromatographic assay cassette.

[0008] In one embodiment, the lateral-flow chromatographic assay cassette may include a capture ligand capable of capturing and localizing at least one analyte of interest in a sample on an analysis surface of the lateral-flow chromatographic assay cassette, at least one reporter configured for interacting with at least one of the analyte of interest or the capture ligand, and at least a first calibration standard and a second calibration standard configured to provide at least a two-point calibration curve.

[0009] In another embodiment, the lateral flow chromatographic assay cassette may include a test strip and a separate calibration strip. In this embodiment of a lateral flow chro-